



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-F-1539]

DSM Nutritional Products; Food Additive Petition (Animal Use); Ethoxyquin; Environmental Assessment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an environmental assessment filed by DSM Nutritional Products in support of their petition proposing that the food additive regulations be amended to provide for the safe use of ethoxyquin in vitamin D formulations, including 25-hydroxyvitamin D<sub>3</sub>, used in animal food.

ADDRESSES: Submit electronic comments to: <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Isabel W. Pocurull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6853.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 23, 2013 (78 FR 77384) FDA published notice that a food additive petition (FAP) had been filed by DSM Nutritional Products, 45 Waterview Blvd., Parsippany, NJ 07054. The petition (FAP 2276) proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 Food Additives Permitted in Feed and Drinking Water of Animals (21 CFR part 573) to provide for the safe use of ethoxyquin as a chemical preservative in vitamin D formulations, including 25-

hydroxyvitamin D<sub>3</sub>, used in animal food. In that document, FDA noted that the petitioner had requested a categorical exclusion from preparing an environmental assessment or environmental impact statement under 21 CFR 25.32(k).

Upon further review and request by FDA, the petitioner has filed an environmental assessment. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the Agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see ADDRESSES) for public review and comment.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) electronic or written comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the Agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the Agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.51(b).

Dated: November 6, 2014.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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